

### **Remarks**

Claims 1, 3, 10-21, 24-26, 28, 30-31, 33-34, 36, and 38-41 are presented for the Examiner's review and consideration. In this Response, claims 1, 11, and 30 are amended, claim 2 and 37 are cancelled, and claim 41 is added. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

#### **35 U.S.C. §102 Rejection**

Claims 1-3, 10-11, 18-20, 30, 32-35, and 37 were rejected under 35 U.S.C. §102(b) as being anticipated by Li (U.S. 5,505,735, "Li"). Initially, Applicant notes that claims 2 and 37 have been cancelled herein, rendering the rejection as to these claims moot. With respect to the remaining claims, for reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

Li discloses an anchor which includes "a body and a plurality of barbs located in circumferentially spaced relation about the body...the barbs extend radially outwardly of the body toward a configuration wherein the barbs are located generally parallel to the longitudinal axis of the body. A diametrical opening in the front portion of the anchor is provided for engagement by a length of cord-like material such that the anchor may be pulled into a bone tunnel, and an opening in the rear portion of the anchor is provided for attaching either a ligament, tendon or the like to the anchor..." (Abstract).

As recited in Li, "...the anchor is pulled into and then along the bone 5 tunnel by pulling on the free ends of the suture-like material. As this occurs, the anchor's barbs will yieldably engage the surrounding bone so as to permit the anchor, and hence the repair material, to be pulled along the bone tunnel until it reaches a desired position. At the same time, however, the anchor's barbs will prevent the anchor from being withdrawn from the bone tunnel in the direction from which it entered." (C5L7-13).

As further stated in Li, "A bore 26 extends through front portion 18, perpendicular to longitudinal axis 15. Bore 26 is sized such that a strong suture 28 (FIG. 1), or some other

suitable anchor pulling means, may be connected thereto for pulling anchor 12 in a forward axial direction. In addition, tapered grooves 27 extend forwardly from the openings of bore 26 onto outer surface 24. Grooves 27, combined with the rounding of the outer edges of bore 26, provide a smooth, substantially continuous surface against which the anchor pulling means 28 may bear. This reduces the chance of breaking the anchor pulling means 28 during deployment of the anchor.” (C6L22-25).

Thus, Li discloses an opening in the front portion of the anchor for pulling the anchor. The front portion is sized for a “strong suture”, and as described and shown in Li, for example in Fig. 5, the strong suture *pulls* the anchor forwards along the bore. Indeed, with the projections as described, this is the only direction in which the anchor *can* be pulled.

In the instant invention claim 1 recites that “said body portion *and* said end portion having a second passage formed therethrough”; claim 24 recites that a “body portion having a first passage...proximate said pointed end” as well as a second passage through the body; claim 30 recites a “passage is formed in said body portion *and* said pointed portion” as in claim 1; and new claim 41 recites “a second passage formed within a transition between said body portion and a beginning of said tapering of said tapering end portion”. Accordingly, in the instant invention, the passage extends at least through a portion of the body of the implant of the invention. As such, the implant of the invention would not work in the application of Li, as a strong suture positioned through the second passage would *increase* a transverse dimension of the implant at the body, and would therefore *impede* forward movement of the implant further along the bore axis, and *increase* a likelihood of suture breakage. As may be seen in the illustrations of Li, the opening in the front portion is always fully within the tapered portion, and therefore a strong cord would have room to pass through the opening without increasing an overall dimension of the anchor in Li. Accordingly, Li does not suggest or teach, and in fact teaches away from, the specific positioning of the passage as recited in the independent claims of the instant invention.

The instant invention provides for positioning of a passage in the implant body for advantageous toggling of the implant within a bore in body tissue, whereby the implant does not tend to pull back out of the bore, nor jam within the bore, but rather toggles with a minimum of

displacement along a longitudinal axis of the bore. In this manner, a suture may be secured within, for example, a blind hole.

Accordingly, Applicant respectfully submits that claims 1, 24, 30, and 41 are patentable over Li. As claims 3 and 10-21 depend from claim 1; claims 25-26 and 28 depend from claim 24; and claims 31, 33-34, 36, and 38-39 depend from claim 30, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §102 rejection.

#### 35 U.S.C. §103 Rejection

The following claims were rejected under 35 U.S.C. §103(a), as being unpatentable over their respective cited references:

claims 12-17, 21, 26, and 36 over Li;

claim 24 over Li in view of Schwartz (U.S. 6,306,159, “Schwartz”), and Hayhurst (U.S. 4,741,330, “Hayhurst”);

claim 25 over Li, Schwartz, and Hayhurst, and further in view of Egan (U.S. 6,106,545, “Egan”);

claim 28 over Li, Schwartz, and Hayhurst, and further in view of Huxel (U.S. 6,503,259, “Huxel”);

claim 31 over Li in view of Whittaker (U.S. 5,417,712, “Whittaker”);

claim 38 over Li in view of Hayhurst;

claim 39 over Li and Hayhurst, and further in view of Egan; and

claim 40 over Li in view of Schwartz.

With respect to claim 24, Schwartz is cited, *inter alia*, for a suture being passed through first and second passages. Applicant notes, however, that Schwartz discloses two implants connected by a suture. With respect to neither implant is it suggested or taught to have an

opening in a body portion *and* a pointed portion, as described above with respect to the instant invention. Accordingly, Schwartz does not correct the deficiencies of Li with respect to claim 24, as described above. It is further noted that in Schwartz, needle 80 inserts a device; Schwartz does not suggest or teach piercing body tissue with an implant, as recited in claims 24 and 41. Moreover, in Schwartz, toggling does not occur within a bore, as recited in claim 41.

Hayhurst is cited for teaching a retainer having a first configuration in which the retainer is freely slidable along the suture and a second configuration in which the retainer is secured and connected to the suture for maintaining the tension in the suture. Egan is cited for teaching a retainer connected to a suture that is made of a material that becomes flowable when ultrasonic vibratory energy is applied so that no knot is required to fix the suture in place. Huxel is cited for teaching a force distribution member being disposed between a retainer and body tissue. Whittaker is cited for teaching a suture passage may extend at an acute angle to the longitudinal axis. It is noted that bone engaging means 45 of Whittaker are operative to prevent rotation in a manner similar to Li. Hayhurst, Egan, Huxel, and Whittaker additionally do not cure the deficiencies of Li as described above, at least with respect to a position of the passages, and an ability to rotate/toggle within a bore. As such, Applicant respectfully submits that no combination of the cited references operates to produce the instant invention as claimed.

Accordingly, Applicant respectfully submits that claims 1, 24, 30, and 41 are patentable over a combination of Li, Schwartz, Hayhurst, Egan, Huxel, and Whittaker. As claims 3 and 10-21 depend from claim 1; claims 25-26 and 28 depend from claim 24; and claims 31, 33-34, 36, and 38-39 depend from claim 30, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references for at least the same reasons.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the §103 rejection.

#### Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding

this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

Fees for an extension of time, an RCE, and an extra independent claim are believed to be due, and is being paid together herewith. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 782-A03-003-1)

Respectfully submitted,

/ Paul D. Bianco /

Paul D. Bianco, Reg. 43,500

Customer Number: 33771  
FLEIT GIBBONS GUTMAN BONGINI & BIANCO  
21355 East Dixie Highway, Suite 115  
Miami, Florida 33180  
305-830-2600, fax 305-830-2605, pbianco@fggbb.com